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Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,156,067 was filed on July 1, 2009, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BRYAN®cervical disc system (PMA No. P060023), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.<sup>1</sup> Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

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<sup>1</sup>The filing of the application on July 1, 2009, was timely, given the NDA approval date of May 12, 2000. Applicant, however, misidentified at section 4 on page 2 of the application the last day the application may be submitted as July 4, 2009, pursuant to 37 C.F.R. § 1.740(a)(5), however, that date is day 54 in the sixty-day period of section 156(d)(1).. Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus July 10, 2009, or sixty days from May 12, 2009, starting the count of the sixty-day period on May 12, 2009. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

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